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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/544,776	04/07/00	WEI D	1561.003/200

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CHIRON CORPORATION
INTELLECTUAL PROPERTY - R440
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EXAMINER	
ZARA, J	
ART UNIT	**PAPER NUMBER**
1635	12

DATE MAILED: 09/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/544,776	WEI ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-10,23-25,28 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-10,23-25,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

KATRINA TURNER
PATENT ANALYST

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

This Office action is in response to the communication filed June 29, 2001, Paper No. 11.

Claims 1, 2 and 5-29 are pending in the instant application.

This application contains claims 11-22, 26 and 27 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 2, 5-10, 23-25, 28 and 29 have been examined as indicated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendments and Arguments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claims 1 and 5-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record set forth in the Office action mailed February 26, 2001, Paper No. 8.

Applicant's arguments filed June 29, 2001 have been fully considered but they are not persuasive. The claims are drawn to isolated nucleic acids molecules encoding polypeptides which comprise subsequences of SEQ ID NO: 2, as well as comprising polynucleotides at least 80% identical to the aforementioned polynucleotides and comprising at least one conservative amino acid substitution of the aforementioned polypeptides. Applicants argue that adequate description has been provided in the instant specification (i.e. at pages 11 and 15) for the sequence variations claimed. Contrary to Applicants' assertion, the instant specification does not describe a representative number of sequence variations of SEQ ID Nos: 1 or 2, whereby the NogoB polypeptide is stably and functionally expressed in an unaltered state. No motifs or domains have been adequately described whereby 20% of the polynucleotides are altered and Nogo B is expressed. No data has been provided for the tolerance of conserved amino acid changes of SEQ ID NO: 2 whereby Nogo B is expressed and its function conserved. The specification describes the number of polynucleotide or amino acid substitutions that are preferred for patentability, but no data has been provided to establish that these preferred ranges of sequence changes yield polynucleotides or polypeptides which are functionally equivalent to Nogo B.

Claims 23-25, 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of inhibiting cell growth in vitro comprising the administration of antisense or ribozymes targeting nucleic acids encoding Nogo B, does not

reasonably provide enablement for methods of inhibiting cell growth of Nogo B expression in vivo comprising the administration of antisense targeting nucleic acids encoding Nogo B, for the reasons of record set forth in the Office action mailed February 26, 2001, Paper No. 8.

Applicant's arguments filed June 29, 2001 have been fully considered but they are not persuasive. Applicants argue that the instant specification is enabling for antisense or ribozyme in vivo delivery and target inhibition because it would not be unpredictable to predict the therapeutic efficacy of antisense or ribozymes because in vitro target inhibition has been provided. Contrary to Applicants' assertions, there remains a high degree of unpredictability regarding the extrapolation of in vivo efficacy from in vitro data of antisense or ribozymes administered, as illustrated in the references provided in the Office action of February 26, 2001 (See especially Bioworld Today, page 1, left column). No in vivo data has been provided in the instant specification for the successful delivery and inhibition of target gene expression in an organism following the administration of any antisense or ribozymes which target SEQ ID NO: 1. Therefore the instant invention stands rejected for lacking enablement over the scope claimed, which scope includes in vivo delivery and inhibition of target gene expression.

Claims 23, 24, 28 and 29 are rejected under 35 U.S.C. 103(a) for the reasons of record set forth in the Office action mailed February 26, 2001, Paper No. 8.

Applicant's arguments filed June 29, 2001 have been fully considered but they are not persuasive. Applicants argue that Bandman et al do not disclose the entire polynucleotide

sequence of SEQ ID NO: 1 and therefore it would not have been obvious to design and utilize antisense or ribozyme molecules which target and inhibit the expression of Nogo B, as in the methods described by Milner et al or James. Contrary to Applicants' assertions, Bandman et al disclose polynucleotides comprising over 600 nucleotides of SEQ ID NO: 1, which polynucleotides are shared between SEQ ID NO: 1 of the instant application and the previously disclosed NSPLP of Bandman et al. Bandman et al disclose antisense and ribozyme molecules which target portions of the target nucleic acid molecule encoding NSPLP, and which include over 600 nucleotides of SEQ ID NO: 1 (See especially columns 27 and 28 of Bandman et al). It therefore would have been obvious for one of ordinary skill in the art to design and assess the ability of antisense or ribozymes to target and inhibit the expression of the previously disclosed target molecule NSPLP which includes over 600 nucleotides of carboxy terminus of Nogo B, as listed in SEQ ID NO: 1.

Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 112

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what the "coding region of SEQ ID NO: 1" is. Clarification is required.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ANDREW WANG
PRIMARY EXAMINER

JZ

September 21, 2001